

REMARKS

This Response Under 37 CFR §1.115 is respectfully submitted in response to the Office Action rendered June 16, 2005. This Response is timely in view of the concurrently filed Petition for Extension of Time. Claims 15-22 are pending and Claims 1-14, 17 and 23-29 are canceled.

The Office Action of June 16, 2005 rejected Claim 22 under 35 U.S.C. §102(a) as being as anticipated by Kelly et al. (WO 99/36050) ("Kelly"). The Office bases this rejection upon the following reasoning:

Kelly et al. teach using soy extract for protecting skin from UV damage. See Abstract. The soy extract of Kelly et al. is obtained by the extraction with a mixture of organic solvents and water. See p. 11, lines 23-27. The recitation of "non-denatured" soy product is inherent in the reference because the soy beans are extracted without using enzymes and/or temperature. The compositions of Kelly et al. may also contain preservatives. See p. 10, lines 8-9.

Thus, Kelly et al. teach each and every limitation of Claim 22. [Office Action, page 2]

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants respectfully observe that Kelly does not disclose a "non-denatured" soy product as alleged in the Office Action. Applicants' Specification sets forth their understanding of the term "non-denatured" at p. 7, l. 10, as follows:

What is meant by "non-denatured soy product" is a soy product in which the processing for the derivation of such soy product (e.g., the temperature, extraction media) **did not eliminate its protease inhibitory activity.** (Emphasis added)

The Specification states that deionized or purified water is the preferred extraction solvent. The Specification further indicates that ethanol/water mixtures may be used, but only if the ethanol be removed in such ways that the protease inhibitory activity of the soybean will be retained. [Specification, p. 7, l. 16 through p. 8, l. 5]

Kelly indicates that extracts of soy or clover containing isoflavones may be prepared according to WO93/23069, the teachings of which were incorporated by reference. As described in WO93/23069, soy or clover may be extracted with a mixture

of **organic solvent** (such as ethanol, chloroform, acetone, ethyl acetate and the like) and water. [Kelly, p. 11] Kelly details the extraction process at p. 17 of WO93/23069, in Example 1 ("Preparation of Red Clover Product"), as follows:

The raw plant material is harvested and dried; such drying being either sun-drying or from applied heat....**The dried material is extracted in an aqueous organic solvent mix.** The aqueous phase is required to extract the water-soluble glycoside form of isoflavones, while the organic solvent is required to solubilise the water-insoluble aglycone form. The organic solvent can be either alcohol, chloroform, acetone or ethyl acetate. The ratio of solvent in the water can be between 0.1% and 99.9%. The preferred method is to use 60% alcohol in water." [Kelly, p. 17] (Emphasis added)

In contrast, applicants' claimed invention requires a **non-denatured soy product**, in which the protease inhibitory activity of the soy product has **not** been eliminated by processing. The non-denatured state is measured by the presence of an intact soybean trypsin inhibitor (STI) protein. As set forth in the Declaration of Dr. Miri Seiberg, filed concurrently herewith, it was known at the time of invention that proteins, including soy proteins, are denatured in the presence of ethanol. [Seiberg Declaration, ¶¶3-5]. Therefore, they would not have expected the Kelly extract to contain active proteins such as serine protease inhibitors. Thus, they would not have been led to the compositions of applicants' invention through the Kelly reference.

Applicants respectfully submit that the soy extract set forth in Kelly is **not** non-denatured and the recitation of a "non-denatured" soy product is not inherent in Kelly as the Office Actions asserts. Applicants therefore respectfully request reconsideration of the foregoing rejection.

The Office Action of June 16, 2005 also rejected Claims 15-21 as being unpatentable over Tokuyama (JP 5-320061), in view of Mizue (JP 62-36304). The Office bases this rejection upon the following reasoning:

Tokuyama teaches using aqueous or organic extract of soy beans and/or other legumes in unaltered form in topical dermatological compositions for treating a variety of skin diseases and conditions such as scratches, cuts, burns, rashes, eruptions, pimples, blackheads, chapping skin, eczema, dermatitis, etc. See Abstract; [0009]; [0010]; [0033], table 4; [0036]. Moreover, the soy bean extracts applied to the skin as cosmetic products showed a "smoothing effect on the texture of the skin", "a wrinkle stretching rejuvenating effect", skin softening and moisturizing effect and "an aging preventing effect". See [0045]-[0047]. With respect to Claim 17, the compositions of Tokuyama have a "beautifying

effect” on the skin, i.e. inhibit tyrosinase activity. See [0048]. (Please note that the term “beautifying effect” is often used in Japanese publications as synonymous to “skin whitening effect”). With respect to Claim 20, the reference teaches inhibiting sebum production. See [0035]; [0045]. With respect to Claim 21, Tokuyama teaches “smoothing effect on the texture of the skin” and anti-aging effect. See [0045]. With respect to the limitation “non-denatured”, the Tokuyama reference teaches the same extraction method as disclosed in the instant application. See Examples 2 and 3. Therefore, the soy product of Tokuyama is inherently non-denatured. The Tokuyama does not explicitly teach the stabilizing system of the instant claims. However, Mizue teaches stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA. See p.6 of the translation; Examples. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cosmetic or dermatological soy extract-containing compositions of Tokuyama such that to add chemical agents such as preservative. One of ordinary skill in the art would have been motivated to do this to prevent spoilage of the soy extract suggested by Mizue. [Office Action, page 3]

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants respectfully request clarification as to the Mizue reference. The translation for JP 62-36304 indicates the inventor to be Katsumi Mizumaki, not Mizue, with the title of the invention being “A Cosmetic Material”. Applicants respectfully presumed for purposes of this Response that “Mizue” refers to JPB 62-36304.

Tokuyama discusses oxygen eliminating agents derived from legumes. [0009] Specifically, Tokuyama mentions an active oxygen elimination agent characterized in that it is “a[n] aqueous extract or an organic solvent extract from legumes or a juice from fresh legumes in unaltered form or in that it contains them”. [0010] Tokuyama also indicates that the components are stable in the presence of heat. [0013]

As set forth above, “non-denatured soy product” is a soy product in which the processing for the derivation of such soy product (e.g., the temperature, extraction media) did not eliminate its protease inhibitory activity.”

Applicant respectfully submits that the invention of Tokuyama is different from that in instant application. Tokuyama did not recognize the importance of maintaining the STI activity and is not concerned that the extract retain serine protease inhibitory

activity. Rather, Tokuyama uses heat and extraction procedures which are known to denature proteins, thereby eliminating protease inhibitory activity.

In making the rejection, the Office Action acknowledges that Tokuyama does not explicitly teach the stabilizing system of the instant claims. [Office Action, page 3-4]

Nor does Mizue compensate for the inadequacies of Tokuyama in directing those of ordinary skill in the art toward applicants' claimed invention. The Office Action relied on Mizue to teach stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA. [Office Action, page 4] The Office Action then concluded that it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the cosmetic or dermatological soy extract-containing compositions of Tokuyama to add chemical agents such as preservatives. One having ordinary skill in the art would have been motivated to do this to prevent spoilage of the soy extract as suggested by Mizue. [Office Action, page 4]

Applicants respectfully submit that Mizue, taken together with Tokuyama or separately, would not render the compositions and methods of applicants' invention obvious. Although Mizue discusses means for preserving soy extracts present in a composition, it does not provide means for obtaining the non-denatured, active STI-containing extracts of the compositions of applicants' invention. In particular, the extract of Tokuyama is not a non-denatured extract. To combine Tokuyama with Mizue would not have lead to a topical, skin care composition comprising a soy product in which the soy product was a non-denatured soy product.

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In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of June 16, 2005. An early allowance is earnestly solicited. Kindly direct any questions or contacts to the undersigned.

Respectfully submitted,

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